Subject recruitment notice

The U.S. Army Aeromedical Research Laboratory is conducting a study on refractive surgery in the Army Aviation environment. At present, refractive surgery is not waiverable for Army Aviation; therefore, entry into the Army Rotary Wing Aviator Training Program with refractive surgery requires an aeromedical refractive error exception to policy. Applicants must complete specific requirements to be considered for the exception to policy. The study is designed to evaluate individuals who had photorefractive keratectomy (PRK) or laser in-situ keratomileusis (LASIK), are at least nine months postoperative, and have demonstrated stability of their vision. There are specific limits as to the amount of correction that is allowed: no more than 6 diopters of myopia correction or 4 diopters of hyperopia correction, and no more than 3 diopters of astigmatic correction. In addition to Snellen visual acuity and cycloplegic refraction, USAARL will complete other tests to assess the surgical changes of the cornea and vision as part of the study enrollment process. Individuals must meet all other requirements for medical fitness for Army flying duties, including any residual visual acuity and refractive error.

Study candidates who need more information on the protocol should read the enclosures in this PDF document and contact LTC Corina van de Pol at 334-255-6876, or via email corina.vandepol@se.amedd.army.mil.

Information sheet

Exception to policy process for Evaluation of Refractive Surgery for Army Aviation Study

Background

The US Army Aeromedical Research Laboratory (USAARL), in coordination with the US Army Aeromedical Activity (USAAMA) and Army Aviation Branch, is conducting a study on selected Army aviator students to evaluate certain corneal refractive surgeries for compatibility with the Army Aviation environment. The study goal is to determine whether certain corneal refractive surgeries should be approved procedures for Army Aviation. If you are interested in participating in the study, you must meet preliminary qualifications, in addition to having an otherwise qualified Class 1W/1A Flying Duty Medical Examination (FDME) before application to Army aviator training. Photorefractive keratectomy (PRK) and laser in-situ keratomileusis (LASIK) are the only two procedures approved for study. Other refractive error correction procedures, to include radial keratotomy (RK) and corneal implants (Intacs®), will not be studied. Aviator training applicants who had refractive surgery must participate in the research study in order to receive an aeromedical refractive surgery study exception to policy to enter Army aviator training. The informed consent form below provides additional information about the study.

Preliminary requirements

Study applicants must meet the following consideration criteria.

1. The applicant s PRK or LASIK surgery must be completed nine months prior to initiating the Class 1W/1A FDME for aviator training application.

2. The surgical correction must be no greater than 6 diopters of myopia correction or 4 diopters of hyperopia correction in any meridian by refraction transposition, and no greater than 3 diopters of astigmatism correction.

3. The Class 1W/1A FDME cycloplegic refraction must be stable and within Class 1W/1A medical fitness standards.

4. The Class 1W/1A FDME corrected visual acuity must be within Class 1W/1A medical fitness standards.

5. The cornea must be free of visually significant haze.

6. The corneal shape must be free of irregularities and the ablation must be centered.

7. Contrast sensitivity must be within the normal range.

8. The applicant must be free of postoperative effects, such as corneal ulcers, eye pain, blurred vision, visual glare or flare, halos around lights or objects, night vision aberrations, etc.

Initial verification process prior to aviator training application: Applicants must complete the following aeromedical requirements for Army aviator training application.

1. The applicant will provide their corneal surgeon with a request for release of medical records.

2. The corneal surgeon will forward the requested medical records to US Army Aeromedical Research Laboratory, ATTN: LTC van de Pol, Bldg 6901, Fort Rucker, AL, 36362, for review.

3. USAARL will review the medical records and provide the Director, USAAMA, with written recommendations and copies of the medical records. Applicants who do not have a favorable recommendation from USAARL will be aeromedically disqualified from application to the Army aviator training program and denied an aeromedical refractive surgery exception to policy.

4. The applicant and local military flight surgeon will complete a Class 1W/1A FDME and submit the FDME to the Commander, US Army Aeromedical Center, ATTN: Director, US Army Aeromedical Activity, Bldg 301, Fort Rucker, AL 36362. The Director, USAAMA, will review the FDME, USAARL s written recommendations, the corneal surgeon records, and make a final written determination of medical fitness for flying duties. The Director, USAAMA, will return the FDME and written approval of preliminary qualification for the study protocol to the local military flight surgeon for enclosure in the applicant s Aviator Selection Board packet. Applicants who do not have an otherwise qualified FDME will be aeromedically disqualified from application to the Army aviator training program and denied an aeromedical refractive surgery exception to policy.

Aeromedical refractive surgery exception to policy for aviator training process: After an applicant is accepted for Army aviator training and arrives at Fort Rucker, the aviator student must complete the following requirements to formally enter the study protocol and finalize the aeromedical refractive surgery study exception to policy.

1. USAAMC Aviation Medicine Clinic will complete a verification FDME, request an aeromedical refractive surgery study exception to policy, and forward the documents to the Director, USAAMA.

2. USAARL will complete the study human use protocol with subject registration, consultation, informed consent for the Evaluation of Refractive Surgery for Army Aviation Study.

3. USAARL will complete study enrollment vision tests, including corneal topography, contrast sensitivity, glare disability and corneal physiology. USAARL will provide the Director, USAAMA, with written recommendations and copies of the examination records. Applicants who do not have a favorable recommendation from USAARL will be medically disqualified and eliminated from the Army aviator training program, and denied an exception to policy.

4. The Director, USAAMA, will review the FDME, USAARL s written recommendations, and make a final written determination of medical fitness for flying duties. Applicants who do not have an otherwise qualified FDME will be aeromedically disqualified, aeromedically eliminated from the Army aviator training program, and denied an exception to policy.

Request for Release of Medical Records

From: _____ Date: _____
_____

To: _____
_____
_____

Subject: Request release of medical records related to refractive surgery procedure

1. I am considering participation in a research study of refractive surgery in Army aviator training students. I request a copy of records pertaining to my refractive surgery be provided to:

LTC Corina van de Pol, O.D., Ph.D.
US Army Aeromedical Research Laboratory (Visual Science Branch)
Bldg 6901, PO Box 620577
Ft. Rucker, AL 36362

Voice: (334) 255-6876 and Fax: (334) 255-6993

2. For your convenience, please complete the attached data sheet. The data sheet requests specific information related to the following:

Date of procedure
Type of procedure (only PRK or LASIK)
Type of laser
Ablation parameters
Amount of correction
Pre-operative refraction and date
Follow-up refractions and dates
Subjective assessment of corneal clarity/haze
Corneal topography maps
Contrast Sensitivity or low contrast acuity
Visual Acuity

3. Please contact Dr. van de Pol if you have any questions.

_____ _____
Printed name of the study applicant Signed name of the study applicant

Study applicant
Last name: _____ First name:_____ Middle initial:____

Date of Birth _____ Contact Tel. #: _____

Eye Care Provider
Name: _____ Date of report: _____

Clinic address & telephone: _____
_____

Specific procedure details

Date of Procedure: _____ Type *(circle one)*: PRK or LASIK
Laser Used: (manufacturer)_____ (model #) _____

Ablation parameters (Complete below, or if available, attach copies of laser records)
OD: Size of ablation: _____ *mm* Tissue removed: _____ *microns* # of Pulses: _____
OS: Size of ablation: _____ *mm* Tissue removed: _____ *microns* # of Pulses: _____

Amount of correction programmed into laser
OD: _____ OS:_____

Pre-operative Refraction
OD:_____ OS:_____

Did the applicant require any enhancement procedures? Yes _____ No _____
(If yes, please provide details, as above)

Follow-up examinations (include most recent and 2 prior examinations)

Date	Refraction	Visual acuity	Corneal haze* (circle one)
	OD_____ OS _____	OD_____ OS_____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD_____ OS _____	OD_____ OS_____	OD 0 1 2 3 4 OS 0 1 2 3 4
	OD_____ OS _____	OD_____ OS_____	OD 0 1 2 3 4 OS 0 1 2 3 4

*** Haze 0-4 scale**. 0=no haze, 1=trace, 2=minimal, 3=moderate, 4=iris details obscured.

Corneal topography (include copy of most recent corneal topography using the TANGENTIAL or INSTANTANEOUS map display option)

Topographer used:
Manufacturer: _____
Model: _____
Date of topographies: _____

Contrast sensitivity (attach copy of results, if available)

Test Used:
Manufacturer: _____
Model: _____

Date of contrast test: _____

Test Conditions:
Room Lights ON (circle one) Yes No
Backlit Chart (circle one) Yes No
Distance to test _____m
% Contrast (if letters) _____%

Results:
OD _____
OS _____

Thank you for completing the information. Please return this form and supporting records to:

LTC Corina van de Pol, O.D., Ph.D.,
US Army Aeromedical Research Laboratory
Bldg 6901, PO Box 620577
Ft. Rucker, AL 36362

Tel: (334) 255-6876
Fax: (334) 255-6993

Informed Consent Agreement

VOLUNTEER AGREEMENT AFFIDAVIT:
For use of this form, see AR 70-25 or AR 40-38; the proponent agency is OTSG.

Authority:	Privacy Act of 1974, 10 USC 3013, 44 USC 3101, and 10 USC 1071-1087
Principal purpose:	To document voluntary participation in the Clinical Investigation and Research program. Social Security number (SSN) and home address will be used for identification and locating purposes.
Routine Uses:	The SSN and home address will be used for identification and locating purposes. Information derived from the study will be used to document the study; implementation of medical programs; adjudication of claims; and for the mandatory reporting of medical conditions as required by law. Information may be furnished to Federal, State, and local agencies.
Disclosure:	The furnishing of your SSN and home address is mandatory and necessary to provide identification and to contact you if future information indicates that your health may be adversely affected. Failure to provide the information may preclude your voluntary participation in this Investigational study.

Part A Volunteer affidavit for volunteer subjects in approved Department of Army research studies

Note: Volunteers are authorized all necessary medical care for injury or disease that is the proximate result of their participation in such studies under the provisions of AR 40-38 and AR 70-25.

I, ___XXXXX SAMPLE XXXXX_____ SSN: _XXXXX SAMPLE XXXXX____,

having full capacity to consent and having attained my _____ birthday, do hereby volunteer to participate in the study entitled **Evaluation of refractive surgery for Army Aviation** under the direction of **LTC Corina van de Pol, O.D., Ph.D.** conducted at the **U.S. Army Aeromedical Research Laboratory, Fort Rucker, Alabama, 36362**.

The implications of my voluntary participation, duration and purpose of the research study, the methods and means by which it is to be conducted, and the inconveniences and hazards that may reasonably be expected have been explained to me by **LTC Corina van de Pol, O.D., Ph.D., Primary Investigator, 334-255-6876 or DSN 558-6876.**

I have been given an opportunity to ask questions concerning this investigational study. Any such questions were answered to my full and complete satisfaction. Should any further questions arise concerning my rights or study-related injury, I may contact the **USAARL Human Use Committee Representative, Dr. Patricia LeDuc, at U.S. Army Aeromedical Research Laboratory, Ft. Rucker, Alabama, 334-255-6872 or DSN 558-6872.**

I may at any time during the course of the study revoke my consent and withdraw from the study without further penalty or loss of benefits; however I may be required (military volunteer) or requested (civilian volunteer) to undergo certain examinations if, in the opinion of the attending physician, such examinations are necessary for my health and well-being. If I have had PRK or LASIK, my entry into Initial Entry Rotary Wing (IERW) training will be with an aeromedical refractive surgery study exception to policy approved by the U.S. Army Aeromedical Activity. If I decide to withdraw from the study, continuance of the exception to policy will be reviewed by the U.S. Army Aeromedical Activity, Ft. Rucker, AL. If I have not had PRK or LASIK, I may withdraw from the study at any time. My refusal to participate will involve no penalty or loss of benefits to which I am otherwise entitled.

Subject initials __XXXXX__ Witness initials __XXXXX__

Part B To be completed by the Primary Investigator

Note: Instruction for elements of the informed consent provided as detailed explanation in accordance with Appendix C, AR 40-38 or AR 70-25.

Purpose

The purpose of this study is to evaluate military occupational-specific characteristics of both visual and flight performance of Initial Entry Rotary Wing (IERW) candidates who have had photorefractive keratectomy (PRK) or laser in-situ keratomileusis (LASIK) and to determine if PRK and/or LASIK are acceptable, waiverable procedures for Army Aviation.

Aeromedical refractive surgery exception to policy for PRK and LASIK subjects

Since refractive surgery is not currently a waiverable procedure for entry into flight school, you will be given an aeromedical refractive surgery study exception to policy through the U.S. Army Aeromedical Activity (USAAMA). This exception to policy will remain in effect during the course of the study and upon completion of the study will be reviewed annually by USAAMA using the same procedures for other vision waivers. Such a policy process is already in place for trained aviators who wear contact lenses. Circumstances that may lead to loss of the exception to policy are the same as those for any other flight program participants, including a significant decrease in vision or other changes in the health of your eyes.

Procedures

If you participate as a subject, we will measure your vision under normal lighting, low lighting and glare conditions, the shape of your cornea, the aberrations of your eye, the clearness of your cornea, the health of your cornea, and your pupil size. The eye test portion of the study will take 3 to 4 hours and will be completed at enrollment into the study, 3 months, 6 months and 12 months after enrollment and again 12 months after completion of flight training.

The initial phase of all testing will involve measurement of the refractive error of your eyes (a standard clinical measurement to determine your spectacle prescription). We will then measure your vision using visual charts set at a distance of 6 meters and at a distance of 40 centimeters. The procedures are the same as a standard clinical visual acuity exam in that you will cover one eye at a time with a cover paddle and will be asked to read the letters on the chart. Vision will be determined with full room lighting on and with the room lighting set at a dim level. Glare disability is determined by having you read letters on a chart at 2 meters mounted on a box that has bright backlighting. The glare source is produced by standard incandescent light bulbs behind a translucent plexiglass sheet and is not bright enough to cause harm to the eye.

For the following three tests you will place your chin on a chin rest, your forehead against a headrest, and look at a target in the instrument. The tests take less than 1 minute per eye. The shape of your cornea will be measured using a clinical instrument that shines a series of narrow beams of light onto the cornea and captures images at specific positions of the cornea. The aberrations of your eye will be measured using an instrument that shines an array of lights into your eye and measures the light that is reflected back into the instrument from your eye. The clearness of your cornea is determined using an instrument that captures two images of your cornea using a short flash of a narrow slit beam on the cornea. The short flash of light is not harmful to the eye, but you will notice a brief afterimage of the beam.

The health of your cornea will be determined using an instrument which takes an image of the back surface of your cornea and analyzes the shape, number and size of the cells (Clinical Specular Microscope). Prior to taking the measurement, we will instill one drop of topical anesthetic into each eye.

The anesthetic is a standard clinical anesthetic; it stings briefly and then numbs the surface of the eye. The instrument has a smooth probe that will be placed against the front surface of the eye to take the image. The procedure is not dangerous to the eye. However, in rare cases individuals may have an allergic reaction to the anesthetic or slight irritation from the probe. You will be asked each time before this procedure whether you have ever had a reaction to an anesthetic. If so, the test will not be performed. The cornea will be checked after this test to ensure that neither the anesthetic nor the probe of the Clinical Specular Microscope has affected the front surface of the eye. The size of your pupil will be measured using a hand-held instrument that you look into. Your pupil size will be measured in full room lighting and again under dim light conditions.

Flight performance information will be recorded using standard procedures in flight school; specific information required for this study will be provided to the researchers by the Standards Management Officer in each training battalion. As part of this research, you agree to allow USAARL representatives access to your flight performance data.

Benefits

You will receive no benefits from participating in the study, other than the personal satisfaction of supporting Army Aviation vision research.

Risks

Clinical testing: You are encouraged to ask questions before, during and after the testing. You may take breaks or request a delay in testing at any time without fear of retribution. All of the procedures are used in clinical eye examinations. Effects of specific instruments were described in the Procedures section above. If you have a reaction to the anesthetic or develop any corneal irritation from the probe used with the clinical specular microscope, you will be treated immediately. The treatment will consist of artificial tears (if the irritation is minor), or topical antibiotic drops, dilating drops, and eye patch (if the irritation is more severe). You will be checked again every 24 hours until the cornea is healed (note: the cornea is normally healed in less than 24 hours).

Flight School: Failure to meet flight school requirements, either due to a change in the condition of your eyes or flight performance, will require standard administrative actions to remove you from flight school and does not differ from actions for any other flight candidate.

Follow-on Studies

The Army s research on refractive surgery will extend beyond this study. Therefore, you may be asked to participate in follow-on studies. Your participation in follow-on studies is entirely voluntary and whether you decide to participate, or not, does not impact your status in this study. Any other studies will have a separate protocol and a separate consent form and are not considered part of this study.

Confidentiality

All data and medical information obtained about you will be considered privileged and held in confidence. Images of your eyes taken with the various clinical instruments will not be identified with any of your personal information (name, rank, or status). All examinations will be recorded using a subject identifier code and a separate file with your consent form and your assigned subject identifier code will be kept in a locked cabinet, only accessible by the Primary Investigator. Complete confidentiality cannot be promised, particularly if you are a military service member, because information bearing on your health may be required to be reported to appropriate medical or command authorities. In addition, applicable regulations note the possibility that the US Army Medical Research and Materiel Command (MRMC) officials may inspect the records.

The Volunteer Registry Database

It is the policy of the U.S. Army Medical Research and Materiel Command that data sheets are to be completed on all volunteers participating in research for entry into this Command s Volunteer Registry Data Base. The information to be entered into this confidential database includes your name, address, Social Security number, study name and dates. The intent of the database is twofold: first, to readily answer questions concerning an individual s participation in research sponsored by USAMRMC; and second, to ensure that the USAMRMC can exercise its obligation to ensure research volunteers are adequately warned (duty to warn) of risks and to provide new information as it becomes available. The information will be stored at USAMRMC for a minimum of 75 years.

Withdrawal from study by investigator

You may be withdrawn from the study if you are unable to participate in the examinations. However, every effort will be made to ensure that time is available in your flight school schedule to allow you to participate and at no time will you be required to miss training to participate in the study. Additionally, you may be withdrawn from the study and flight school if your vision deteriorates during the course of the study to a level deemed unsafe by the investigator and verified as unsafe by the clinical medical monitor. This is in no way different from current flight school standards.

I do do not *(Circle one & initial)* consent to include this form in my outpatient medical treatment record.	
Signature of the volunteer XXXXX SAMPLE XXXXX	Date
Permanent address of the volunteer XXXXX SAMPLE XXXXX	
Signature of the witness XXXXX SAMPLE XXXXX	Date
Typed name of the witness XXXXX SAMPLE XXXXX	